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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,976	06/15/2001	Matthias Rath	11957/2	8960

26646 7590 06/12/2002

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group/Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-11 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-11 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, part b is unclear. What is the "one or more signal oligopeptides within the structure of the disease causing protein" the same as the "one or more signal oligopeptides representing the amino acid sequence of maximum hydrophilicity"?

Claim 10, part b is unclear. What is the "one or more signal oligopeptides within the structure of the disease causing protein" the same as the "one or more signal oligopeptides representing the amino acid sequence of maximum electrical charge"?

Claim 11 is unclear as to what happened to parts a-c.

Claim 11, part e is unclear. What is the "one or more signal oligopeptides within the structure of the disease causing protein" the same as the "one or more signal oligopeptides representing the amino acid sequence of maximum electrical charge"?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. There does not appear to be a written description of the claim limitations of identifying a protein responsible for causing disease, identifying the signal oligopeptides, the evolutionary chain method, producing different immunogenic responses in humans, selecting the vaccine oligopeptide produced by the animal which produced the desired response in humans, and the various claimed modifications of the oligopeptide in the application as filed. Applicant has not described proteins that are causative of disease nor the use of specific signal sequences to treat disease.

Claims 1-11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is merely a hypothetical description of something desirable. There are no specific examples set forth in the specification. While applicant is not required to set forth working examples, the specification must set forth sufficient teachings to allow one to practice the claimed invention. The specification does not teach how to select "signal oligopeptides" that would be useful for a vaccine. The specification is not clear on what constitutes a signal oligopeptide. The specification indicates that peptide regions of high hydrophilicity are signal oligopeptides. The art recognizes that signal sequences can also be hydrophobic and that hydrophilic regions are not necessarily signal oligopeptides. See Watanabe et al. *JOURNAL OF BIOLOGICAL CHEMISTRY*, and Hogh et al. *PARASSITOLOGIA*, (abstracts only, provided in a parent application). It is not clear how one is to define a particular protein that is responsible for a given pathological condition. It would be an undue burden to expect the artisan to find the one particular protein responsible for any given human disease that would be amenable to the instant treatment absent specific guidance. It is further unclear how a signal oligopeptide can be used as a vaccine. There are no teachings in the specification as to what form the vaccine must take and what

components are required in the vaccine. It is unclear from the specification if the oligopeptide acts directly to treat the pathological condition or if the oligopeptide induces an immune response to treat the condition. There is no evidence in the specification that peptides that fall within the claims would induce a differential response and that the response would treat the disease. Further, what algorithms are required to ascertain which amino acid sequences would be useful?

In short, applicant's specification is only speculation that something desirable can be done without providing any objective evidence to support enablement of the claimed invention. The instant specification is an invitation to experiment and is not enabled for the invention as claimed.

The claimed invention is apparently free of the art of record.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

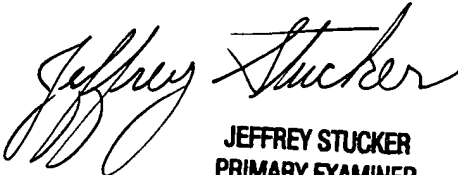
Serial Number: 09/881976
Art Unit: 1648

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JEFFREY STUCKER
PRIMARY EXAMINER